U.S. Department of Agriculture

Office of Inspector General
Southeast Region

Audit Report

Oversight and Security of Biological Agents at Laboratories Operated by the U.S. Department of Agriculture

Policies and Inventories Are Needed To Manage Biosecurity

Report No. 50099-13-At
March 2002

UNITED STATES DEPARTMENT OF AGRICULTURE
OFFICE OF INSPECTOR GENERAL
Washington D.C. 20250

DATE: March 29, 2002

REPLY TO
ATTN OF: 50099-13-At

SUBJECT: Oversight and Security of Biological Agents at Laboratories Operated by the U.S. Department of Agriculture

TO: William Hawks
Under Secretary
Marketing and Regulatory Programs

Joseph Jen
Under Secretary
Research, Education, and Economics

Elsa Murano
Under Secretary
Food Safety

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Under Secretary
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Lou Gallegos
Assistant Secretary
for Administration

This report presents the results of the subject review. Your written responses to the draft report are included as exhibits with excerpts and the Office of Inspector General's position incorporated into the relevant sections of the report. The written responses contained sufficient justification to reach management decision on Recommendation No. 5. Please follow Departmental and internal agency procedures in forwarding final action correspondence to the Office of the Chief Financial Officer.

Based on the responses, management decision has not been reached on Recommendations Nos. 1, 2, 3, 4, 6, 7, 8, 9 and 10. The information needed to reach management decision is set forth in the OIG Position section after each recommendation. In accordance with Departmental Regulation 1720-1, please furnish a reply within 60 days showing the actual or planned timeframes for implementing each audit recommendation. Please note that the regulation

requires a management decision to be reached on all findings and recommendations within a maximum of 6 months from report issuance, and final action to be taken within 1 year of each management decision.

We appreciate the courtesies and cooperation extended to us by members of your staff during the review.

Joyce N Fleischman

JOYCE N. FLEISCHMAN
Acting Inspector General

Executive Summary

Oversight and Security of Biological Agents at Laboratories Operated by the U.S. Department of Agriculture (Audit Report No. 50099-13-At)

Results in Brief

Recent terrorist acts in this country, including the anthrax attacks on Government and media officials, underscore the importance of security over biological agents—organisms that in the wrong hands could pose a risk to human health and agricultural production in the United States. Because of its mission, the U.S. Department of Agriculture (USDA) performs research and diagnostic testing in laboratories across the country in which it uses and stores agents that could potentially be used in terrorist attacks.

We began our audit of USDA laboratories in April 2001. Our objectives were to determine the extent and location of agents that are pathogenic to humans or injurious to agriculture, the adequacy of procedures to guard against the accidental or illegal release of these agents, and the adequacy of security to prevent unauthorized access and removal of the agents. The events of September 11, 2001, gave new urgency to our review.

USDA operates approximately 336 laboratories throughout the country. The biosafety levels of the agents used or stored in the laboratories are classified according to their risk of harming animals or plants—high risk if causing potentially lethal infection, low risk if posing little danger of infection.[1] High risk agents include those known to be zoonotic—transmissible from animals to humans. Most USDA laboratories use or store moderate or low risk agents. Some use or store high risk agents.

We found that security of biological agents at USDA laboratories was inconsistent and generally in need of improvement. Before September 11, biosecurity was not a major concern at the laboratories because previous break-ins did not appear to result in the theft of biological agents. Moreover, the Department's emphasis had been on ensuring that laboratory personnel were protected against biological agents, rather than ensuring that such material was not accessible to unauthorized individuals. Consequently, the Department had issued no policies and procedures for agencies to implement to manage security at the laboratories and to centralize control of field unit practices involving the use and storage of biological agents.

Of particular concern was the absence of a consolidated database to allow agency managers to identify the location and risk levels of the biological agents at laboratories across the country. Without such a database, agency

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[1] The Department adopted its biosafety level classifications from the Centers for Disease Control and Prevention, whose guidance was limited to those biological agents posing a risk to humans. The Agricultural Research Service applied this guidance to agents posing a risk to plants and animals.

managers cannot determine if the containment and security at the laboratories is commensurate with the risk associated with the agents. Indeed, during recent Federal attempts to track down the source of the strain of anthrax used in the October 2001 anthrax mailings, USDA officials were unable to immediately determine whether the Department used or stored that strain. Although the laboratories themselves are required to maintain an inventory of their biological agents, only some did so, and some of those we reviewed were not accurate. At one major laboratory with high risk agents, eight of the nine agents we reviewed did not match inventory records. According to an official at this laboratory, one vial listed in inventory but not found in storage contained about 3 billion doses of *Vesicular stomatitis virus*, a pathogen of considerable risk to humans and cattle. This laboratory had not updated its inventory of high risk agents since 1997.

The absence of a centralized database has already resulted in post-September 11 misinformation and improper reporting. During the month of October, the Secretary, acting on information provided by agency officials, reported to the Office of Homeland Security that one laboratory known for its work with high-risk agents was no longer using the agents. We found that the laboratory continued to store and experiment with Bluetongue virus and *Vesicular stomatitis virus*, both of which are considered zoonotic and restricted agents by the Centers for Disease Control and Prevention. However, we also noted that anthrax was not used or stored in any location not designated for it.

We reviewed the security of 124 USDA laboratories located at 91 sites across the country. Security measures at almost half of these sites needed improvements of some sort. Alarm systems, security fences, and surveillance cameras were commonly lacking. Previous internal security reviews had identified many deficiencies, and laboratory directors were generally aware of the necessary upgrades, but these were slow in coming due to funding constraints and pre-September 11 management priorities. For example, a security survey conducted at several Department laboratories recommended perimeter fencing, but while the lower risk laboratories got the fencing, funding constraints left the higher risk laboratories without. Additionally, some field laboratories that were not near their central facilities, such as one laboratory situated in a strip mall, appeared to be at greater risk because of their locations. Such laboratories should be consolidated with more secure facilities.

The Department also did not adequately control access to biological agents by personnel entering the laboratories. At several laboratories, scientists and researchers not associated with USDA work had ready access to units where biological agents were stored. Some of the scientists and researchers were non-US citizens. Not all of the laboratories had received any post-September 11 instructions regarding access by visiting researchers or

others with keys to the laboratories. Because of a backlog of security background checks, access was routinely granted to researchers whose background checks had not been completed. A lack of policy on background checks resulted in access inconsistencies. One laboratory official considered a visa as fulfillment of the agency's requirement for a background check.

Finally, the Department needs to institute procedures for laboratories to report to their agency headquarters any incidences of unauthorized access. Although laboratories are currently required to report vandalism or break-ins to OIG and the Department's Office of Crisis Planning and Management, there is no requirement that the laboratories inform their agency managers of these incidents. In practice, some laboratories have only been informing the local police. Without specific reporting requirements, agency officials cannot manage the security of their laboratory networks and cannot know when security levels are inadequate.

Recognizing the need for greater biosecurity in the wake of the September 11 attacks, the Secretary assigned a task force to develop policies and procedures for biosecurity issues within the Department. The task force's goal was to draft standards in four key areas: inventory control, physical security, personnel security, and biosecurity incident response. On November 9, 2001, the Deputy Secretary signed the decision memorandum for the Secretary of Agriculture adopting the policies and procedures developed by the task force and directed USDA agencies to implement them. Currently, USDA agencies are drafting plans to implement the policies and procedures. The document establishes policy for all pathogens deemed of particular sensitivity by USDA, whether those pathogens had previously been identified as high risk or not. The Department is currently finalizing the policies and procedures into a Departmental Regulation.

During our audit, additional congressional funding has been forthcoming to strengthen the Department's biosecurity programs. On January 10, 2002, President Bush signed the Defense Appropriations Act, which included $328 million for USDA for security upgrades and other activities in response to terrorist attacks. Emphasizing protection of the Nation's food supply, the Act designates $119 million for the Animal and Plant Health Inspection Service (APHIS), $113 million for the Agricultural Research Service (ARS), and $15 million for the Food Safety Inspection Service (FSIS). The remaining $80 million is designated for other USDA homeland security priorities. These funds should help USDA attain the high level of security needed to keep biological agents from falling into the wrong hands.

Note: Because of the sensitivity of the issues contained in this report, we have presented our findings in general rather than specific terms. We have refrained from naming any of the laboratories we visited or specifying any of their locations. A separate document containing this information will be

presented to Department managers for their use in implementing our recommendations.

Recommendations In Brief

We are recommending that the Department hasten the implementation of the policies and procedures established by its task force and that it complete a centralized database of all its biological agents. Once the database is complete, agency managers need to assess the risks associated with each laboratory site and determine what security measures are needed to mitigate those risks. Agencies also need to revisit previous internal security reviews and, with the additional funding provided by Congress, implement corrective actions immediately. One such action would include relocating the laboratory currently situated in a strip mall.

We are recommending that agencies limit access to high risk or high consequence biological agents, and that the Department determine what security background checks are needed for personnel with such access. The Department also needs to reduce the backlog of background checks.

We are recommending that the Department correct the inventory and security problems at the laboratory that the Department inaccurately reported as no longer using high risk or high consequence biological agents.

Finally, we are recommending that the agencies issue a notice to all laboratories to report any break-ins or vandalism to the appropriate Federal officials.

Agency Responses

The agencies responded that they either have controls in place or are instituting controls to bring their laboratories into compliance with the Department's new policies and procedures. They also responded that, for the most part, their laboratories have either taken inventories of biological agents on hand or are in the process of doing so. Both ARS and APHIS acknowledged that they plan to perform a risk assessment once their inventories are complete. FSIS, the Forest Service, and the Agricultural Marketing Service (AMS) stated they had already completed a risk assessment.

Increased security has been provided at those high-risk laboratories that had previously been found deficient. The laboratory located in a strip mall is going to be relocated to a more secure area. ARS and APHIS stated that since September 11, they have communicated with their laboratories on all security issues, including reporting incidents to the appropriate officials. AMS stated it is confident that security and control measures in place are appropriate.

Regarding background checks and unlimited access to biological agents, both APHIS and ARS responded that these issues are covered in the policies and procedures developed by the USDA task force. Both agencies stated that they plan to implement these policies and procedures, as long as funding is not a concern.

OIG Position

While we acknowledge that most of the agencies have put forth a determined effort to improve communications with their laboratories and to implement the Department's new policies and procedures, we also concluded that more needed to be done in several key areas. The most prominent area is a centralized database. Such a database is critical to Department-level management of biological agents, and we urge the agencies to finish consolidating their inventories at the agency and Department levels.

We also urge all agencies to adhere to the doctrines of the task force policies and implement those policies at all laboratories with biological agents, not just those classified as high-risk.

Actions necessary to accept the Department's and agencies' management decisions are provided in the Recommendation sections of the report. The Department's and agencies' written responses are included as exhibits A, B, C, D, E, and F of the report.

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Background and Objectives

Background

Through its various agencies, USDA carries on research or diagnostics of animal and plant diseases at its own facilities throughout the United States. The Agricultural Research Service (ARS) operates the largest number of laboratories, 243 at 113 locations, and the Forest Service operates 77 at 67 locations. Other agencies have fewer laboratories. For example, the Animal and Plant Health Inspection Service (APHIS) has four laboratories at three locations, and the Food Safety and Inspection Service (FSIS) has four laboratories at three locations.

Biological agents are living organisms in their microbial form. Those used in USDA research and diagnostics are generally pathogenic, or disease-producing, to some degree. Citrus canker, for example, is pathogenic to citrus crops but not to animals or humans. Similarly, Foot and Mouth Disease is pathogenic to animals but not to plants or humans. USDA scientists work with both animal and plant pathogens that pose a threat to U.S. agriculture. They also work with pathogens, such as Avian influenza virus, that are regarded as zoonotic. These can cause disease, even death, in both animals and humans.

The Centers for Disease Control and Prevention (CDC) assigns to each biological agent that is considered harmful to humans a biosafety level (BSL) that indicates what laboratory equipment and practices are needed to ensure containment of that agent. Laboratories that work with agents that have a low risk of infecting people are classified as BSL-1 laboratories. Laboratories that work with agents of moderate risk (e.g., *E. coli, Salmonella*)[2] are classified as BSL-2. Laboratories that use agents that may cause lethal infections as a result of exposure by inhalation (e.g., Rift Valley Fever)[3] are classified as BSL-3. *Bacillus anthracis* (anthrax), the agent used in mailing attacks that resulted in several deaths, is considered a BSL-2 agent in the strain used in USDA laboratories.

Adopting the criteria used by CDC to arrive at a BSL-3 classification, ARS has developed a category for BSL-3Ag agents. The ARS listing for this classification includes additional agents (such as viruses, bacteria, and toxins) that are considered potentially lethal to animals and plants. Although CDC classifies Bluetongue virus and other like pathogens as BSL-2 agents, ARS regards them as having considerable consequence to agriculture and classifies them as BSL-3Ag agents.

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[2] These examples were taken from the CDC list of BSL-2 agents.

[3] This example was taken from the CDC list of BSL-3 agents.

USDA laboratories that study practices like soil and water management or forest management are not assigned a biosafety classification because the material they work with is not considered a biological agent.

We began our audit in April 2001, well before the terrorist attacks on September 11. At that time, we focused our work on ARS and APHIS, since they appeared to use and store the majority of biological agents as well as those agents that were classified at the highest biosafety level. However, the events of September 11 and the subsequent anthrax attacks on Government and media figures gave greater urgency to our work and persuaded us to increase our scope and accelerate our fieldwork. On September 13, Congress amended an appropriations bill to require the President "to undertake appropriate actions to enhance the standards for the physical protection and security of biological pathogens…at research laboratories in the United States that create, possess, handle, store, or transport such pathogens in order to protect against the theft or other wrongful diversion of such pathogens." Conditions that may not have reflected serious deficiencies before September 11 had to be viewed more critically thereafter.

Of most concern to us was the absence of a centralized database that agency managers could use to determine where biological agents were located and what security measures would be appropriate for each location. On September 24, 2001, after visiting 10 laboratories at 4 sites, we issued a management alert to the Under Secretaries for Research, Education, and Economics, and for Marketing and Regulatory Programs, recommending among other things that the Department's agencies establish such a centralized database and use it to assess the security risk at each site.

During the month of October 2001, the Secretary, acting on information provided by agency officials, reported to the Office of Homeland Security that the Department had secured all research buildings, laboratories, pathogens, and personnel. The Secretary also stated that an ARS laboratory that had previously been using BSL-3 agents was no longer doing so. Departmental documentation noted, however, that agencies still had no centralized inventory of the biological agents under their control, a fact confirmed by our own field reviews. We consequently questioned the basis for the agencies' assurances to the Secretary.

To answer these questions, we visited another 114 laboratories located at 87 sites[4] to determine if the laboratories were appropriately secured and if the agencies had contacted their laboratories as a result of our September 24 management alert. We found that the situation had not significantly changed;

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[4] Sites often house more than one laboratory. It is not unusual to find several laboratories with different biosafety classifications located side by side at the same site.

few laboratory officials had been contacted by their agency managers, and security at the laboratories had not significantly increased. We issued a second management alert to this effect on December 10, 2001.

Objectives

The objectives of the audit were to determine (1) the extent and location of materials that are either pathogenic to humans or are pests to agricultural production, (2) the adequacy of procedures to protect employees and the public against accidental or illegal releases of hazardous organisms, and (3) the adequacy of security to prevent or minimize unauthorized access and removal, including by theft or terrorist attack, of pathogenic organisms from departmental facilities.

Findings and Recommendations

Section 1. Department Oversight

Finding 1

Lack of Emphasis on Biosecurity Resulted in No Departmentwide Policies or Procedures

Until recently, the Department had not formulated policies or published procedures for the security of biological agents at the laboratories it operated. Prior to September 11, 2001, the Department's emphasis was on biosafety—ensuring that laboratory personnel were protected from the biological agents they handled—rather than on biosecurity—ensuring that such materials were safeguarded against unauthorized access or release. Without policies and procedures, the Department had no consistent oversight of biosecurity activities and no centralized control of field unit practices concerning the use and storage of biological agents.

We met with agency officials in April 2001. We learned that with few exceptions, the responsibility for dealing with accidents and attacks was fragmented among the various laboratory units. Laboratories generally did not report security issues to their agencies, and agencies did not report issues to the Department.

Most of the laboratories are located on Federal property throughout the United States. Those laboratories using biological agents classified as BSL-3 or BSL-3Ag are required to follow CDC security guidelines and ARS direction.[5] Otherwise, the individual laboratories decide on security issues based on their levels and needs. Some agencies have engaged security experts to assess the level of security needed. For example, the Department contracted with an outside organization, the Sandia National Laboratories, to assess the vulnerability of seven laboratories that work with high consequence agents and toxins. ARS has also contracted with the Army to review security at one of its major BSL-3 laboratories and offer insights to enhance the protection of this facility.

USDA facilities on colleges and universities are generally located in buildings owned by the institution, although some of the buildings are Federal property. Access is not restricted on the college and university campuses and security at these locations is dependent on the campus security officers. Laboratories on campuses are typically more open and accessible than those housed on Federal property. Students allowed in the laboratories are registered with the college or university, but not with USDA, and security

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[5] For simplicity, this report will use the BSL-3 classification in reference to all biological agents and laboratories classified by ARS as BSL-3Ag or by CDC as BSL-3.

background checks are not consistently performed on individuals who are granted access to biological agents.

Although we could find no departmentwide policy on biosecurity, we were able to identify specific guidance on issues of biosafety. The USDA Safety and Health Manual establishes an occupational safety and health program to protect Department employees, the public, and the environment from the risks of occupational safety and health hazards and to prevent damage to physical property. The safety and health programs are organized at the agency level. Each agency may adopt the manual as the required written occupational safety and health program or supplement the manual to comply with specialized regulatory requirements, which may apply to an individual agency's work. In practice, the agencies further delegated implementation of the programs to their field levels. There is no mention of biosecurity in the safety and health manual.

The Department's organizational structure recognizes both biosafety and biosecurity as independent concerns, but it does not offer the same formal emphasis on biosecurity as it does on biosafety. The Department's Biological Safety Committee was established in August 1998, according to the Safety and Health Manual, which also sets forth the committee's responsibilities. This committee consists of officials from various agencies who collectively provide general direction and oversight of the USDA Biological Safety Program. The Biological Safety Committee focuses on employee safety issues, however, and not on biosecurity or bioterrorism. The Department's Biosecurity Committee, by contrast, existed about 1 year. It was subsequently absorbed by the Department's Homeland Security Council Working Group. As an independent committee, the office combined the former functions of personnel security, national security, and emergency management at USDA. The office staffed an emergency management team and did background checks on employees in sensitive positions. According to the director of the Office of Crisis Planning and Management, who had chaired the Biosecurity Committee, the committee had issued no directives or policies during his tenure.

We noted that at least two USDA agencies, ARS and APHIS, have been involved in a Federal interagency working group on biosecurity since the group was formed in January 2001. The group, which includes representatives from at least five other Federal departments, was constituted to establish biosecurity standards analogous to those that already existed for biosafety. However, membership in this group by APHIS and ARS did not translate into tighter controls within the agency or into a wider awareness of biosecurity within USDA.

Recognizing the need for greater biosecurity in the wake of the September 11 attacks, the Secretary assigned a task force to develop policies and procedures for biosecurity issues within the Department. This task force included representatives from ARS, APHIS, the Office of Inspector General, the Office of the General Counsel, and the Office of Budget and Program Analysis. The task force's goal was to draft standards in four key areas: inventory control, physical security, personnel security, and biosecurity incident response. On November 9, 2001, the Deputy Secretary signed the decision memorandum for the Secretary of Agriculture adopting the policies and procedures developed by the task force and directed USDA agencies to implement the policies and procedures in those four key areas. The Department is currently finalizing the policies and procedures into a Departmental Regulation. In the interim, USDA agencies have been drafting plans to implement these policies and procedures.

Although establishing policy for USDA-held pathogens at BSL-3 facilities, the task force document acknowledges that it also pertains to other "high consequence pathogens," as determined by the Department. The task force defines "high consequence pathogens" as "those that are not restricted to BSL-3 laboratories but are nevertheless deemed of particular sensitivity by the USDA—*Bacillus anthracis* is an example." The task force document thus extends Department policy on biological agents to include some pathogens that have historically been designated BSL-2. According to the task force, these high consequence pathogens will be identified and listed by agency administrators.

In support of the policies and procedures, one of the products planned by the Sandia National Laboratories in their assessment of laboratory security is a Biosecurity Field Manual and Training Guide. The purpose of the manual is to provide the methodology and framework for assessing and improving the biosecurity of high consequence microbial agents and toxins both within USDA facilities and during the movement of those agents. The Department regards the Sandia project as serving to complement the policies and procedures developed by the task force.

We concluded that the Department should implement the task force policies and procedures as soon as possible to establish consistent management of biosecurity activities and to centralize control of laboratory practices.

Recommendation No. 1

Hasten the implementation of the policies and procedures being prepared by the Department's biosecurity task force.

Agency Responses

FSIS has already established controls at laboratories, and the Forest Service has committed itself to implementing the policies and procedures

immediately upon their issuance. APHIS is in the process of implementing the policies and procedures at all of its laboratories, and ARS is developing biosecurity controls over BSL-3 materials and laboratories. AMS has reviewed the policies and procedures and concluded that measures currently in place are appropriate. Using the new policies and procedures, it will update its Safety and Occupational Health Handbook.

ARS and APHIS formed a working group to draft an implementation plan on biosecurity. The Secretary's office has also directed that a second working group be formed to harmonize the Department's policies and procedures with the security assessments made by Sandia National Laboratories. The second working group is scheduled to complete its task by the end of March. At that point, the first working group will make all necessary adjustments to the draft implementation plan. The ARS Office of Homeland Security will continue to coordinate efforts for the protection of ARS physical and biological assets.

OIG Position

We concur with the actions taken by FSIS, AMS, the Forest Service, ARS, and APHIS to comply with provisions of the Department's policies and procedures for biosecurity.

However, to reach management decision on this recommendation, ARS, APHIS, and the Forest Service need to provide timeframes for implementing their biosecurity plans once their working groups have harmonized the provisions of the Department's policies and procedures on biosecurity with the security assessments made by Sandia National Laboratories. Also, AMS needs to provide a timeframe for updating their Safety and Occupational Health Handbook.

Finding 2

USDA Needs a Consolidated Database to Monitor Biological Agents

The Department did not have a consolidated database to allow agency managers to identify the location and containment level of biological agents at USDA laboratories across the country. Although many laboratories kept inventories of some sort, Headquarters managers did not establish a Headquarters repository for the information. Without such a database, managers cannot assess the risks associated with the individual materials and determine if the current containment and biosecurity levels are appropriate for each. Many laboratories did not keep up-to-date inventories themselves and consequently could not ensure that the security provided was commensurate with the risk involved. Our pre-September 11 review of 10 laboratories disclosed that security was not considered a priority. Of the additional 114 laboratories we visited after September 11, only 34 had materially increased security.

As a first step toward improving laboratory oversight and assessing the risk of unauthorized intrusion and the biosecurity needed to mitigate that risk, each laboratory must know what biological agents it stores. USDA's Biological Safety Policy, dated August 31, 1998, requires laboratories to conduct inventories of biological agents and their toxins within each facility and to identify their effects on humans and the environment. The USDA Safety and Health Manual contain program requirements for compliance with this policy. These include the development of a site-specific, written biohazard control plan. The plan must contain provisions for identifying and accounting for all biological agents and their toxins within the facility.

There is no similar requirement that each agency maintain a centralized database of the agents used or stored at laboratories under their administration. Such a database would not only strengthen management oversight, it would provide for offsite data storage so data could be retrieved in the event the laboratory is damaged or destroyed. To create such a database, comprehensive listings of biological agents at the laboratories must be forwarded to Washington, D.C., and updated on a routine basis.

Agency officials stated that responsibility for maintaining databases of biological agents had been delegated to the individual laboratories. While we found that most individual laboratories did keep inventories of the biological agents they stored, these inventories were sometimes inconsistent and were not consolidated or summarized at either the agency or departmental level into an up-to-date, centralized database that could readily identify the location and risk of the biological organisms. In sum, at the time of our audit, the Department was unaware of the type, amount, and location of all biological agents handled, stored, or produced in connection with its research and diagnostic activities. The Department, therefore, could not provide adequate assurance that such biological agents were appropriately secured.

- Few Laboratories Kept Current Inventories

  We visited 91 sites where USDA laboratories are located. Sixty-two[6] of the 91 sites we visited stored or used biological agents and were therefore required to keep inventories, but only 39 did so, and only 22 of the 39 inventories were updated annually. Generally, individual scientists kept inventories of the materials they used in their own research, but these inventories were not necessarily monitored by laboratory officials, who must determine whether the safeguards in place were adequate. For example, a scientist at laboratory A in our sample had experimented with Salmonella but had retired and left without informing laboratory officials

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[6] Twenty-nine of the sites we visited did not use or store any biological agents.

that the BSL-2 agent was still in their inventory. In subsequent years, the laboratory ceased to operate at the BSL-2 level but still stored the BSL-2 agent.[7]

- Not All Existing Inventories Were Accurate

  Our spot check of available inventory records found six with discrepancies. Inventories at two laboratories continued to list biological agents that were once used at the sites but were no longer in stock. The inventory at a third laboratory listed items that were in stock but were mislabeled. In this case, the actual contents of the vials were of the same biosafety level as the agents erroneously marked on the labels. More notable, however, was the inventory at laboratory B in our sample, which stored both BSL-2 and BSL-3 biological agents. The BSL-3 agents were last inventoried in 1997. For eight of the nine agents we spotchecked, there were either more vials on hand than listed in inventory, fewer vials on hand than listed, or vials on hand with no labels. (According to a laboratory official, one of the missing vials contained about 3 billion doses of *Vesicular stomatitis virus*.)

  An official at laboratory B noted that research assistants sometimes misfile agents, and that research students may introduce viruses in research projects without updating the inventory. The official also said he was not aware of any inventory procedures required by ARS or any strengthened security measures mandated after September 11. (This laboratory was severely deficient in physical security. See Finding No. 3.)

  Officials at all but 1 of the 91 sites we visited were of the opinion that the biological agents they used and stored were appropriately categorized as to biosafety level prior to our September 24 management alert and that they consequently provided adequate safety against accidental exposure of the agents to their staff or the environment. No additional measures had been taken after September 24.

We found that laboratory officials do not always review the accuracy of their biosafety classifications and that without an updated inventory they may not be able to properly evaluate that classification. This was true of both laboratories A and B. As previously noted, laboratory A had ceased to operate as a BSL-2 laboratory even though it continued to store a BSL-2 agent. At laboratory B, we found some BSL-3 agents miscategorized and stored with BSL-2 agents in a BSL-2 storage unit. *Vesicular stomatitis* and

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[7] Laboratory personnel informed our auditors that they would destroy this sample once our review brought it to their attention.

Epizootic hemorrhagic disease were assigned a BSL-2 classification by the laboratory even though ARS has designated them as requiring BSL-3 level containment.

Poorly kept inventories have already resulted in post-September 11 misinformation and improper reporting. During the month of October, the Department reported to the Office of Homeland Security that laboratory B was not using BSL-3 agents. We found that the laboratory continued to store and experiment with Bluetongue virus and *Vesicular stomatitis virus*, both of which are considered BSL-3 agents by ARS and restricted agents by the CDC.

Not all laboratories were aware of the biosafety level of their agents and needed Headquarters guidance to correctly assess the security requirements of their facilities. During our review, we became aware of a case in which AMS headquarters officials themselves did not know the correct biosafety classification of one of their sites. (This site was not one of the locations included in our scope, but conditions at the site were verified by an OIG auditor.) Initially officials at both the laboratory (laboratory C) and at agency headquarters said this laboratory did not contain biological agents and was therefore not assigned a biosafety level. We determined that according to CDC requirements for the agents used and stored at the laboratory (*E. coli* and *Salmonella*), the laboratory should have been classified as a BSL-2 site. This confusion demonstrates the need for greater communication between managers who must administer Department biosecurity and the laboratory personnel engaged in research or diagnostics.

We concluded that a consolidated database is needed to provide the Department and its agencies with better monitoring and oversight of biological agents at USDA laboratory facilities. The Department's new policies and procedures also now require inventory controls. The procedures call for a local inventory, a consolidated or national inventory, and a working inventory (experiments in progress). The consolidated inventory will allow agencies to rapidly identify the facilities at which particular agents are in use.

Recommendation No. 2

Direct all agencies to instruct all USDA laboratories to immediately compile a comprehensive listing of biological agents handled or stored at their respective facilities and to forward this listing to the agency's headquarters for consolidation at the Department level. This inventory record should include all laboratories, by agency, showing the biosafety level for each facility and a current inventory, which easily identifies all biological agents. Ensure that the inventory record is secure and can be readily accessed by managers at the headquarters level. Establish a date for accomplishing this task.

Agency Responses

Prior to September 11, 2001, FSIS and ARS laboratories either maintained inventories of biological agents or had begun taking such inventories. After the terrorist attacks, FSIS laboratories updated their inventories, and ARS expects to complete a validation of its national pathogen inventory by the end of March. The Forest Service stated that it did not work with biological agents dangerous to humans, only with plant and insect disease organisms. The Forest Service will submit an inventory of these organisms to Headquarters by June 1, 2002. APHIS stated that its laboratories met their January 31, 2002, deadline to transmit their inventories to Headquarters. AMS stated on March 18, 2002, that all of its laboratories reviewed and updated their biological agent inventories and forwarded copies to headquarters.

OIG Position

We concur with the actions of FSIS, AMS, the Forest Service, ARS and APHIS to comply with the Department's policies and procedures on biosecurity by maintaining inventories of all biological agents at each lab and consolidating those inventories at the agencies' headquarters level. However, to reach management decision, we need the plan and timeframe for development and implementation of the consolidated inventory for the Department.

Recommendation No. 3

Based on the inventory of biological agents for each facility, each agency should immediately assess the risk associated with such biological agents and determine the commensurate biosafety and biosecurity level for such agents.

Agency Responses

APHIS plans to begin its risk assessment once it has reviewed all the inventories submitted by its laboratories. APHIS expects to complete the risk assessments by July 31, 2002. AMS stated on March 18, 2002, that it reviewed its inventory and found no agents of high consequence and that current security and safety measures in place are sufficient for the materials handled and stored. ARS stated that it has assigned biosafety levels to all 2,365 agents in its national pathogen inventory and will implement security measures in conjunction with the requirements of the Department's policies and procedures.

The Forest Service has conducted or is still conducting risk assessments at its facilities and will implement corrective measures as appropriate. FSIS formed a team of laboratory representatives in September 2001 to assess laboratory operations, and based on the team's critique, it has subsequently enhanced existing security plans.

OIG Position

We concur with the actions taken by FSIS, AMS, ARS, APHIS and the Forest Service to assess the risk associated with biological agents and

determine the commensurate biosafety and biosecurity level for each agent. We agree with the actions of the Forest Service to conduct physical security risk assessments at their facilities. However, to reach management decision for this recommendation, the Forest Service needs to provide us with a timeframe for the completion of the reviews.

Finding 3

Laboratories Can Enhance Their Physical Security With Additional Funding Provided by Congress

Not all USDA laboratories were adequately secured against intrusion by unauthorized personnel. Few risk assessments had been made prior to or immediately after September 11, leaving laboratory and agency officials either unaware of the adequacy of security, skeptical of the recommended upgrades, or uncertain how to fund them. We concluded that biological agents stored at some of the less secure laboratories were vulnerable to theft and misuse. Subsequent congressional funding for homeland security activities has provided the Department with additional means to enhance laboratory security at its facilities.

Officials at only 12 of the 91 sites we visited believed security was inadequate at their sites. In 11 cases, the officials pointed out the absence of alarm systems, security fences, or surveillance cameras. However, we concluded from our observations that security needs were more widespread and that improvements were needed at 41 of the 91 sites. Fifteen sites in our sample had already experienced break-ins and vandalism prior to our visits. Unauthorized persons had entered laboratories to use or steal computers and other equipment, or to release laboratory animals. At one ARS laboratory, the intruder destroyed an experiment in progress by turning the power off. Five break-ins involved BSL-2 laboratories, and one of these five break-ins occurred after September 11. Although officials at the five BSL-2 laboratories that experienced break-ins did not express any concerns that biological material could have been removed, only two of the laboratories had current inventories that could be used to make such a determination. (As stated earlier, we did not find anthrax being used or stored in any location not designated for it.)

Agency managers and officials at most of the laboratories we visited agreed on the need to immediately upgrade the physical security at the facilities to help reduce the risk that ongoing research could be destroyed or otherwise adversely affected by terrorism or vandalism and ensure that hazardous organisms are not released. Some laboratory directors and other staff were aware of security needs and emphasized the unmet security upgrades identified in security surveys. For example, the security survey conducted at several collocated ARS' and APHIS' laboratories recommended perimeter fencing. However, the higher biosafety level laboratories for both agencies remained unfenced during our fieldwork due to funding constraints while the lower level laboratories were fenced. Additionally, some field laboratories that were not near their central facilities, such as the laboratory located in a strip mall, appeared to be at most risk and should be considered for consolidation with more secure facilities. With funds now available for

security upgrades, the Department should ensure that its most urgent needs (i.e., laboratories with moderate and high risk biological agents) are met first.

Based on our interviews with Department and agency officials, we could not identify any one individual at the Department level who was assigned the responsibility for monitoring or reviewing the physical security at these facilities to ensure it was adequate.

We did note, however, that the Department's Office of Procurement and Property Management (OPPM) provided technical assistance in awarding the security assessment contract to Sandia National Laboratories on behalf of ARS and APHIS. Under the terms of the contract, Sandia is performing risk-based evaluations of USDA's seven most sensitive laboratories based on the most probable threat scenarios. OPPM is also managing an effort (using both in-house and contract staff) to survey an additional 90 ARS laboratories and 15 APHIS laboratories.

None of the five BSL-2 laboratories that experienced break-ins have had subsequent intrusions after strengthening their security. In one case, that of laboratory D in our sample, security improvements included a 10-foot-high chain link fence with razor wire established around the perimeter of the compound. This unit has been subject to threats from animal rights groups, but since implementing its security upgrades, it has not experienced a subsequent intrusion.

Physical security at the one site we visited with a BSL-3 laboratory was clearly not commensurate with the risk posed by the biological agents stored in the laboratory. Our review of laboratory B disclosed that there were no security alarms, no regular police patrols in the area, and no alarms to alert facility management of an equipment problem during off-hours. Furthermore, the facility was adjacent to the interstate highway with an exit ramp beside the property, and the microwave security system was disabled because highway traffic set off the alarm. The perimeter fence was only about 8 feet high with no additional barrier at the top, and one of the outer doors to the livestock building was broken and held shut with a bungee cord.

The Department's new policies and procedures set forth a strategy for providing physical security at each of USDA's laboratories with high risk or high consequence pathogens. The policies define the areas needing security—e.g., perimeters, buildings, laboratories—and specify the security devices—e.g., barriers, security guards, key cards—that should be installed in each area.

The practices outlined in the Department's policies and procedures appear to be thorough and stringent and will clearly require some investment of resources. On January 10, 2002, President Bush signed the Defense Appropriations Act, which included $328 million for USDA for security upgrades and other activities in response to terrorist attacks. In anticipation of this funding, the Secretary asked each agency to prepare a plan for allocating the funds. The plans were submitted to the USDA Homeland Security Council to ensure funding of the most critical needs. We recommended priority funding for laboratory security, based on the observations we had made at field sites. The Act emphasizes protection of the Nation's food supply by designating $119 million for APHIS, $113 million for ARS, and $15 million for FSIS. As noted earlier, ARS operates most of the laboratories within USDA. The remaining $80 million in appropriations is designated for other USDA homeland security priorities. These additional funds should help USDA attain the appropriate level of security needed to keep biological agents from falling into the wrong hands.

Recommendation No. 4

Evaluate the results of security reviews conducted at two of the Department's BSL-3 laboratories (laboratories E and F) and begin implementing corrective actions related to security issues immediately. Arrange for security reviews of other USDA laboratories, starting with level-3 facilities.

Agency Responses

ARS stated that it has increased security at laboratory E by adding armed security guards and requesting routine Coast Guard boat patrols. ARS has also contracted through OPPM to review security at all locations not covered by the Sandia project. The agency expects 34 sites to be completed by April and the rest by September. Security guards and patrols have also been deployed by APHIS at laboratory F, and security reviews have been completed at other APHIS laboratories and corrective actions began shortly after September 11. AMS stated it does not handle or store BSL-3 or high consequence materials. AMS feels the current security and safety measures in place are sufficient for materials handles and stored. Although the Forest Service stated that they have no BSL biological agents, physical risk assessments are being conducted or have been completed at most Forest Service facilities. FSIS, as part of its accreditation under the International Organization for Standardization, implemented safeguards to enhance security at its laboratories. FSIS also established a laboratory security team to identify and evaluate security issues. Also, FSIS stated that its Quality Assurance Division conducts unannounced audits at each of its laboratories.

OIG Position

The agencies' responses addressed all of the security issues cited. However, to reach management decision for this recommendation, the Forest Service needs to provide us with a timeframe for the completion of the reviews.

Recommendation No. 5

Immediately assesses the feasibility of continuing current research and diagnostic activities at the facilities located in a strip mall.

Agency Response

With the homeland security funding provided by Congress, APHIS will relocate the strip mall facility to a new location where it will pose a lesser risk to the public and where it can be more adequately secured against unauthorized entry. APHIS estimates that it will take 3-5 years to complete permanent structures for the laboratory at the new location. However, since the audit, all pathogens of consequence have been removed from the strip mall facility to locked, controlled access freezers on the main laboratory campus.

OIG Position

We can reach management decision for this recommendation based on the action taken and planned by APHIS.

Recommendation No. 6

Take immediate action to correct the deficiencies at laboratory B, including the problems in inventory of biological agents, containment procedures, and physical security.

Agency Response

ARS is in the process of correcting the deficiencies at laboratory B. Officials said additional steps will be taken in accordance with the recommendations made by Sandia National Laboratories and will depend on Defense Appropriation Act funds.

OIG Position

We concur with this action. However, to reach management decision for this recommendation, ARS need to provide timeframes for correcting the deficiencies at laboratory B.

Recommendation No. 7

Propose to the Secretary that one individual at the Department level be responsible for monitoring and reviewing the physical security at USDA laboratories to ensure the security is adequate.

Agency Response

The Deputy Assistant Secretary for Administration has pointed to the work of OPPM as evidence of current Department-level involvement in the biosecurity needs of the agencies. The Deputy Assistant Secretary notes that there is an ongoing movement towards centralizing physical security oversight over the laboratories at OPPM.

OIG Position

Although the Deputy Assistant Secretary for Administration indicates that there is ongoing movement towards centralizing physical security oversight over laboratories at OPPM, to reach management decision for this

recommendation, we need a decision from the Department identifying the individual or position at the Department level responsible for monitoring the physical security at USDA laboratories.

Finding 4

Laboratories Did Not Adequately Control Access to Biological Agents

Officials did not always restrict access to their laboratories or to the biological agents stored in the laboratories. At many laboratories, scientists and researchers not associated with USDA research and diagnostic activities could enter the laboratories and storage units where biological agents were accessible. Some of these scientists and researchers were non-US citizens. In some cases, laboratories had not received any post-September 11 instructions regarding access by visiting researchers or others with keys to the laboratories. With unrestricted access, unauthorized personnel with knowledge of a laboratory's inventory could remove a biological agent and place it in a terrorist's hands long before the theft was discovered.

All 12 of the laboratory officials who believed security was inadequate at their sites were specifically concerned that access was not restricted and that background checks were not adequately performed on visiting scientists and others.

Background Checks Were Not Adequately Performed

During our discussions and visits with agency officials at both the Headquarters level and at the field laboratories, we noted that a security background check was not completed for all personnel who had access to biological agents. Employees had been given access to these materials pending the background check, but because the Department had a substantial backlog of uncompleted background checks, clearance came months after access was allowed. As a result, agencies could only restrict new employees' access to certain laboratories, escorted or otherwise, or find other jobs for them to do until the checks were completed. Without adequate background checks, the risk that someone may vandalize or destroy ongoing research or laboratory facilities or remove hazardous organisms is increased.

A majority of the sites we visited have foreign scientists or students working in the laboratories, and most of these visiting foreigners have access to biological material. However, about 80 percent of these sites did not do background checks on the visitors. Visiting research scientists and other skilled technicians may be allowed access to the facilities (and the biological agents) based on their prior working experience with facility officials. Furthermore, agency officials have stated that there is no

Department requirement for background checks; consequently, we are uncertain of the adequacy of the checks performed by those few sites that claim to have done them. For example, an official at one site said he considered a visa an adequate background check for a visiting scientist.

The director of the Office of Crisis Planning and Management (OCPM), which is responsible for processing background checks within the Department, said that he had added contract staff to his office to complete the backlog of over 600 requests for clearance. He said that prior to September 11, the process of completing a background check could take up to 2 years. His office is determined to trim that to about 75 days. Requests are received, reviewed, and submitted to the Office of Personnel Management within 2 weeks. The Office of Personnel Management returns the clearances in 30 days, and OCPM takes another 30 days to finish the processing. The director also said that his office does not perform checks on foreign visitors because their records are not available.

Department representatives said that OCPM is working closely with ARS and APHIS to obtain the security clearances and suitability determinations needed for laboratory personnel. They noted, however, that background investigations are a continuing, labor-intensive process because of the need to clear new hires. They said that with the renewed interest Government-wide in personnel security, they anticipated new surges of background investigation requests in the future from the laboratories and throughout the Department.

Physical Access Was Not Always Restricted

Officials also needed to restrict access to their BSL-2 laboratories. For example, the ARS research site which houses laboratory A provided keys to some of its laboratories to a contractor to perform custodial service after hours. Because the issue of custodian access to the laboratories was not part of our scope, we do not know how widespread this practice is, and we do not know what kind of background checks, if any, are performed on custodians. At laboratory B, students, professors, and laboratory assistants not associated with ARS research or diagnostic activity could obtain the key to the BSL-2 laboratory and use it even when authorized personnel were not present. A laboratory official also noted that students who had graduated may not have always turned in their keys. The locks had been last changed about 5 years before the audit.

An official at laboratory B stated that the facility needed many improvements to assist in preventing unauthorized access and intentional release of biological agents; however, no action had been initiated or planned by the agency at the time of our review. An official at laboratory

> G in our sample also expressed a need for greater security and controlled access. He said that although the gates to this BSL-3 laboratory were guarded by day and the buildings locked by night, he questioned the competence of the contract guards, and he believed the unattended buildings were vulnerable. A BSL-2 freezer in the laboratory was never locked, and the gate guards seldom required identification or passes of any kind to enter. The agency did not require background checks on the scientists working at this laboratory, and none were performed. The laboratory relied on the integrity of the scientists, none of whom wore identification badges in or around the compound.
>
> Although we found that some facilities maintain an inventory list of biological agents being stored, the facilities did not always require the staff to record the removal of any samples from the inventory or their return to inventory. Also, at some locations we visited, employees were not required to wear picture identification or any other type of distinctive badge, making it more difficult to determine who was authorized to be in the laboratory.

We concluded that agencies should review their security procedures to ensure that access to high-level biological agents is controlled and that unauthorized removal of the agents does not occur. We also concluded that the agencies need to determine the necessity for background checks and security clearances for personnel with access to high-level biological agents and to establish a protocol for approving authorized access to such agents. The Department's new policies and procedures also provide for such protocols. The policies and procedures identify the suitability requirements that will determine which positions require clearance, and they outline escort procedures for all personnel that do not have clearance.

We also concluded that agencies need to work with the Department to reduce the backlog of security clearances.

Recommendation No. 8

Immediately review security procedures to ensure access to high consequence biological agents is controlled and limited to authorized purposes. Institute management controls to ensure that unauthorized removal does not occur by restricting access to facilities and laboratories handling or storing such high consequence biological agents only to personnel with authorized access and with the appropriate identification and requiring specific tracking of any removal and return of samples of high-level biological agents.

Agency Responses

ARS participated in the Department's task force to develop policies and procedures for laboratories containing BSL-3 agents and other high consequence pathogens. The new policies and procedures establish generic

requirements and protocols for physical security, personnel security, and emergency response plans and are in the process of being implemented at the five BSL-3 laboratories. ARS will implement the policies and procedures at the other laboratories once the risk assessment is completed to identify the agents and locations. APHIS laboratories have already implemented procedures restricting access to pathogens of consequence.

Officials of AMS and the Forest Service stated they do not need to institute any controls because they do not use or store high consequence biological agents. FSIS formed a team of laboratory representatives in September 2001 to assess laboratory operations, and based on the team's critique, it has subsequently enhanced existing security plans.

OIG Position

We concur with the actions of APHIS and ARS to limit access to high consequence biological agents and with the actions of FSIS to enhance its existing security plans. However, in order to reach management decision on this recommendation, the Department needs to define high consequence biological agents. Based on this definition, each agency will need to determine the appropriate security procedures if it handles or stores any high consequence biological agent at its facilities.

Recommendation No. 9

Immediately determine the necessity for background checks and security clearances for those personnel having access to high consequence biological agents, particularly those with access to level-3 laboratories. Establish a protocol for approving authorized access to such materials. Also, work with the Department to reduce the backlog of security clearances.

Agency Responses

ARS has identified 229 positions at BSL-3 laboratories requiring background checks. The agency has requested 180-day temporary clearances for these employees while the background checks are underway. APHIS noted that it has identified all the individuals with access to high consequence biological agents who require full-fledged background investigations. Officials from AMS, FSIS, and the Forest Service said they do not use high consequence biological agents and therefore do not need to establish protocols for approving access.

The backlog of security clearances has been cleared at USDA. The Office of Personnel Management (OPM) has yet to respond to about 400 of the clearances that were forwarded to it for final approval. OPM has estimated that the 229 background checks requested by ARS will take up to 6 months to complete.

OIG Position

We concur with the actions of OCPM to reduce the backlog of background checks. We also concur with the actions of ARS and APHIS to identify

positions requiring background checks. However, in order to reach management decision on this recommendation, the Department needs to define what constitutes a high consequence biological agent. Based on this definition, each agency will need to implement the appropriate personnel security procedures if it handles or stores any high consequence biological agent at its facilities.

Finding 5 Laboratories Had No Procedures to Report Unauthorized Access

The Department has no consistent policy for reporting incidents of unauthorized intrusion to their agency headquarters. Although laboratories were required to report break-ins to several Federal agencies responsible for security and criminal investigation, there was no written requirement to report these incidents to agency headquarters. Generally the low-risk laboratories were unaware of any reporting requirements, and only informed local police when a break-in occurred. Without specific reporting requirements, agency officials cannot manage the security of their laboratory networks and cannot know when security levels are inadequate.

Our review found that responsibilities within the Department for handling biosecurity issues, including response to accidents and attacks, are not centralized.

There are at least four organizations that appear to have overlapping responsibilities; however, there is little coordination or communication among them. Although the Office of Crisis Planning and Management maintained that all incidences at laboratories should be reported to it, we found that personnel at the field sites were often not aware of this reporting requirement. In fact, during a visit to one facility, facility officials were also unaware that the Office of Inspector General should be contacted in the event of vandalism or potentially unauthorized access to the facility. We also found that most laboratories have independently established some type of coordination protocols with local law enforcement agencies to respond to security issues. However, in addition to this coordination, agencies need to ensure that field laboratories also report and coordinate such incidences to the agencies' Headquarters-level officials and to the appropriate Department officials.

The Department's new policies and procedures provide a biosecurity incident response plan. The plan calls for the immediate notification of the agency's incident response chief, who will in turn notify the other responsible offices, notably the Office of Inspector General, the Federal Protective Service, and the local police. In the event of a biocontainment breach, the agency will also notify APHIS and the Office of Crisis Planning and Management.

Recommendation No. 10

Immediately issue a notice to all laboratory facilities with high consequence biological agents that they are to report any improprieties or vandalism involving such materials to the agency's Headquarters office, which will in turn notify the Office of Inspector General and the other relevant offices.

Agency Responses

ARS and APHIS both referred to the Department policies and procedures, which call for reporting intrusions at laboratories. ARS further responded that it has communicated repeatedly with its laboratories, orally and through e-mail, since September 2001, providing all ARS employees with guidance on reporting suspicious activity while on Government premises. APHIS also commented that its primary BSL-3 laboratories have developed an incident response plan and that its laboratories have been provided written guidance on reporting incidents and suspicious activities. The Deputy Assistant Secretary for Administration proposed that OPPM be among the points to which notification of unauthorized access is reported.

Officials from AMS, FSIS, and the Forest Service said they do not use high-level biological agents and, therefore, the recommendation was not applicable.

OIG Position

In order to reach management decision on this recommendation, we need additional information from AMS, FSIS, and the Forest Service as to any instructions or guidance provided to their staff and facilities on reporting improprieties, vandalism, or any unauthorized intrusion. Because of the heightened sensitivity since September 11, proper and coordinated handling of such incidents by all staff is critical. Also, we need specific plans and timeframe for implementing any action by the Department.

Scope and Methodology

Our audit effort was conducted at USDA facilities across the United States. We reviewed the Department's policies and regulations over the control of inventory, containment, and physical security. Our review was conducted from April 2001 through February 2002 and covered activities during this period.

We initiated this assignment as an audit survey to determine whether controls were in place to prevent any accidental or clandestine release of biological agents. Our survey, which initially included visits to 10 USDA laboratories across the country, disclosed that the Department had no policies and procedures in place for facilities to follow in order to prevent the release of biological agents. Therefore, we focused on the individual agencies' management of the security and safety of biological agents.

The terrorist attacks of September 11, which occurred during the course of our audit, did not change our objectives, but induced us to consider more carefully the possibility of unauthorized entry to the laboratories to gain access to biological agents capable of harming the food supply. Our audit consequently came to emphasize the security of these agents.

USDA operates approximately 336 laboratories. Of this total, ARS operates 243; the Forest Service, 77; APHIS, 4; FSIS, 4; and AMS, 8. These laboratories carry out research or diagnostic testing at 194 locations throughout the country.

We visited a total of 124 judgmentally selected laboratories at 91 sites.[8] Because of the sensitive nature of biosecurity at these laboratories, we have refrained in this report from giving either the laboratories' names or their locations. A separate document containing this information will be presented to Department managers for their use in implementing corrective action.

During the first phase of our review, we visited 10 laboratories at 4 sites that were considered the highest risk and stored or used the largest number of biological agents. During the second phase, we visited 114 laboratories at 87 sites that were selected based on their proximity to our audit offices. The total sample included laboratories at 69 ARS sites, 17 FS sites, 3 FSIS sites, 3 APHIS sites, and 1 AMS site.[9] Of the 91 sites, 4 were classified as BSL-3,

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[8] The exact number of sites will vary, depending on the source of the count and the definition of "site."

[9] Some sites house laboratories from two different agencies. Consequently the number of sites assigned to each of the agencies will in the aggregate exceed the total number of sites visited.

21 were classified as BSL-2, 14 were classified as BSL-1, and 55 were unclassified or were not aware of their BSL.[10]

We also reviewed the biosafety level of one AMS laboratory at a site not included in our sample. We became aware during our audit that agency managers for this laboratory did not know the biosafety classification of the site. An auditor at the site for another purpose verified this report.

Our audit was performed in accordance with generally accepted government auditing standards. To accomplish the audit objectives, we performed the following steps:

- Reviewed applicable laws, regulations, and guidance concerning biological agents,
- Reviewed USDA policies, procedures, and administrative controls concerning biological agents,
- Interviewed officials of the USDA Office of Crisis Planning and Management, the USDA Biosafety Committee, the USDA Biosecurity Committee, the Safety and Health Management Division of USDA's Office of Human Resources, and the Office of Procurement and Property Management,
- Reviewed agency policies and procedures regarding the control of biological agents,
- Visited laboratories selected from all levels of biosafety classification, and
- Interviewed laboratory and agency officials responsible for handling, storing, and disposing of biological agents.

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[10] Laboratories that do not use or store biological agents do not have an assigned biosafety classification. Furthermore, sites may house several laboratories, each with a different biosafety classification. For purposes of this review, if a site housed multiple laboratories, we assigned the site the highest biosafety classification that any one of the laboratories at the site had.

Exhibit A

Response to the Draft Report From the Deputy Assistant Secretary for Administration

USDA

United States
Department of
Agriculture

Office of the
Assistant Secretary
for Administration

1400 Independence
Avenue SW

Washington, DC
20250-0103

March 15, 2002

Memorandum

To: Joyce Fleischman
Acting Inspector General

From: John Surina
Deputy Assistant Secretary for Administration

Ref: 50099-13-At

Subject: Oversight and Security of Biological Agents at Laboratories
Operated by the U.S. Department of Agriculture

Overall, we conclude that draft report serves a constructive purpose by helping keep the momentum underway to tighten security at USDA laboratories. Appropriately, the principal responders to this report will be those agencies with ownership of the laboratories. Departmental Administration (DA) is playing a role in assisting those agencies in strengthening the physical security and personnel security at these facilities. We therefore, appreciate the opportunity to comment on the draft report.

The report is written in general terms and is lacking the degree of specificity that would make it an action document. In this particular case, however, we agree that it is appropriate. The sensitivity of the subject matter and the possible uses to which malicious parties could put more specific information justifies the broad-brush approach employed. Implicit in this reasoning is a requirement that more specific information developed by the labs, the parent agencies and your office needs to be protected from public release. Perhaps that message should be explicit in the final report.

Finding 1 speaks to the need to speed the development of Department-wide Policies and Procedures for laboratories. Reference is made to the Committee developing these protocols for the labs working on the most hazardous pathogens. Departmental and Federal regulations are being implemented on personnel security, physical security, as well as access to, and custody of, high consequence pathogens within the labs. We believe that your final report should also acknowledge, for the record, that the Sandia Labs project has served to provide a separate, objective, expert review that serves to validate and complement the work of the P&P Committee. The lab directors, the P&P committee, and Sandia

personnel met on February 21, 2002 and are currently blending the best elements of both efforts.

Finding 2 calls for a consolidated database of biological agents. The report is vague as to what a central system should look like. DA does not criticize this level of generality as it is warranted, not just for security, but also out of recognition that maintaining an inventory of living organic materials that grow, pass through other living things, and expire is not at all the same as keeping an inventory of stable, inorganic materials. As with other details on lab security, such an inventory likely warrants some form of protection against unauthorized release to the public.

We would like to see Finding 3 acknowledge the ongoing security surveys under DA's auspices. DA's Office of Procurement and Property Management (OPPM) entered into a reimbursable agreement with the Department of Energy to employ Sandia National Laboratories to perform risk-based evaluations of our seven most sensitive labs based upon the most probable threat scenarios. This contract was awarded on behalf of ARS and APHIS, but DA serves as Contracting Officer's Technical Representative.

In addition to the seven bio-safety level 3 laboratories addressed in this effort, OPPM is also managing an effort (using in-house and contract staff) to survey an additional 90 ARS labs and 15 APHIS labs. Therefore, in keeping with your Recommendation 7, there is an ongoing movement towards centralizing physical security oversight over our laboratories at OPPM. Given the positive response thus far encountered within ARS and APHIS, we anticipate that our assistance will be welcomed by other agencies with laboratory assets. In this regard, we propose that OPPM be among the points to which notification of unauthorized access is reported per Recommendation 10.

The report, in finding 4, addresses the importance of conducting background investigations on lab personnel so that the Department can reasonably deem them trustworthy either for holding positions of public trust or for access to national security information. DA's Office of Crisis Planning and Management (OCPM) manages the Department's revived Personnel Security Program and is working hand-in-hand with ARS and APHIS to obtain the security clearances and suitability determinations needed for lab personnel holding positions of public trust or requiring access to national security information.

We suggest some elaboration on this topic. While the old backlog has been eliminated, given the renewed interest in personnel security generally, we anticipate new surges of background investigation requests in the future from the labs, and throughout the Department. This will be a continuing, labor-intensive requirement because of the need to clear new hires and the obligation to re-investigate individuals according to an established schedule.

While our present target of 75 days is a dramatic improvement from the two-year timeframe correctly noted for years past, the target is based on the assumption that all requests are for the more costly, expedited process, and that the Office of Personnel Management (OPM) can continue to provide that expedited service on time. We believe that Recommendation 9 will be met through the special procedures that have been established to assure that all lab personnel with access to high consequence pathogens and/or national security information will have appropriate clearances or suitability determinations. For incumbent lab personnel who may need an initial investigation or a re-investigation, a two-step process has been set up to afford a rapid preliminary check followed by the more lengthy conventional procedure.

Please contact me if you would like elaboration on the foregoing.

cc: Assistant Secretary Gallegos
Russ Ashworth
Cliff Oliver

Exhibit B

Response to the Draft Report From the Agricultural Research Service

DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

MAR 15 2002

SUBJECT: Oversight and Security of Biological Agents at Laboratories Operated by the U.S. Department of Agriculture

ATTN OF: 50099-13-AT

TO: Joyce N. Fleischman
Acting Inspector General
Office of Inspector General

FROM: Joseph J. Jen
Under Secretary
Research, Education, and Economics

We have received and reviewed the Draft Audit Report titled as above, Report No. 50099-13-AT, March 2002. ARS had provided comments and information on actions taken in the responses to the September 24, 2001, and the December 10, 2001, Management Alerts, and the response to your letter dated January 22, 2002. Since that time, ARS has taken further actions that are relative to the concerns and recommendations raised in the Draft Report. ARS responds as follows:

- **Response to Recommendation No. 1.**

...Hasten the implementation of the policies and procedures being prepared by the Department's biosecurity task force.

As reported in the REE response to the OIG January 22, 2002, letter, an ARS/APHIS working group submitted a draft Implementation Plan for BSL-3 facilities on January 16, 2002, to implement the provisions of the P&P on Biosafety. Subsequently, the Secretary's Office has directed that a working group be formed to harmonize the P&P with the security assessment made by Sandia National Laboratories. That working group anticipates completing its work by the end of March. Once that activity is completed, the draft Implementation Plan will be revised as needed. The ARS Office of Homeland Security (OHS) will continue to coordinate efforts for the protection of ARS physical and biological assets.

- **Response to Recommendation No. 2.**

...Direct all agencies to instruct all USDA laboratories to immediately compile a comprehensive listing of biological agents.....

ARS completed data collection of a National Pathogen Inventory (NPI) on January 11, 2002. Review, and where needed correction, of the more than 5,000 individual entries was done to ensure consistency of nomenclature, correct misspelled pathogen names, eliminate duplicates within a reporting unit, and permit accurate retrieval of pathogen information. This activity was completed by February 22, 2002. Currently, the draft NPI has reports from 234 Research Management Units for which 137 filed positive reports for pathogens and 97 filed negative reports. NOTE: the number of Units at any point in time may vary as Units are created, eliminated, or consolidated. On March 4, 2002, all Units were advised to review and verify the corrected responses for their unit. Negative responses also require validation. Once the current validation phase is completed, end of March, the NPI will be removed from the web, but will remain available to managers at the headquarters level. All steps in developing, correcting, and validating the NPI were conducted using a firewall and encrypted Internet transmission.

- **Response to Recommendation No. 3.**

...Based on the inventory of biological agents for each facility, each agency should immediately assess the risk associated with such biological agents and determine the commensurate biosafety and biosecurity level for such agents.

The ARS Biosafety Officer has assigned biosafety levels to all 2,365 individual agents in the NPI. Appropriate security measures will be implemented pending the completion of activities described under the response to Recommendations No. 4 and No. 8. Oversight and coordination of facility security for ARS, APHIS, FSIS, FS, and AMS will continue to be provided by the Work Group on Homeland Security, Sub-Council on Protecting USDA Facilities and Other Infrastructure which was appointed by the Under Secretaries of REE and NRE on January 7, 2002.

- **Response to Recommendation No. 4.**

...Evaluate the results of security reviews conducted at two of the Departments BSL-3 laboratories (laboratories E and F) and begin implementing corrective actions related to security issues immediately. Arrange for security reviews of other USDA laboratories, starting with level-3 facilities.

The USDA contracted review of the five BSL-3 facilities was completed by Sandia National Laboratories in December 2001. A draft report was provided to the Department in January 2002. Complete implementation of the Sandia recommendations will first require the harmonization of

the draft report with the Biosecurity P&P and a Phase II contract with Sandia. The response to the January 22, 2002, letter described the ARS initiated contract through the USDA Office of Procurement and Property Management (OPPM) to conduct risk assessments of at all ARS locations not covered by the Sandia or other risk assessment reports. Twenty-two location assessments have been completed, 12 other locations will be visited between March and April 2002, and the remaining locations will be visited between May and September 2002.

Finding 3 in the Draft Report describes the additional resources provided in the Defense Appropriations Act to fund ARS security upgrades. Plans for the use of these funds have been provided to the Department. Release of these funds will be necessary to implement any additional security measures.

- **Response to Recommendation No. 5.**

Recommendation No. 5 concerns APHIS, not ARS.

- **Response to Recommendation No. 6.**

...Take immediate action to correct the deficiencies at laboratory B, including the problems in inventory of biological agents, containment procedures, and physical security.

Steps taken to correct deficiencies were described in the response to the January 22, 2002 letter. Additional steps will be accomplished in Phase II of the and implementation of the Sandia recommendations and will depend on the Defense Appropriations Act funds.

- **Response to Recommendation No. 7.**

Recommendation No. 7 calls for action on the part of the Secretary.

- **Response to Recommendation No. 8.**

...Immediately review security procedures to ensure access to high consequence biological agents is controlled...

No additional comments.

- **Response to Recommendation No. 9.**

...Immediately determine the necessity for background checks and security clearances for those personnel having access to high-level biological agents, particularly those with access to level-3 laboratories...

ARS has completed its initial assessment of mission critical ARS employees having access to facilities containing BSL-3 pathogens. To date, 48 positions have been identified as requiring Personnel Suitability Level-3 (PSL-3) background checks, as described in the Biosecurity P&P, and 181 positions at PSL-2. It is estimated that these background checks from OPM may require up to 6 months to complete at a cost of $575,000. While these background checks are being conducted and in order to continue critical research programs, ARS has requested 180 day temporary clearances from the Department. The ARS OHS and ARS Human Resources Division

are implementing new procedures to speed up and track security clearances and background checks.

- **Response to Recommendation No. 10.**

...Immediately issue a notice to all laboratory facilities with high-level biological agents that they are to report any improprieties or vandalism involving such materials...

No additional comments.

We would be pleased to keep you apprized of progress in these efforts. If you have any questions or concerns, please contact Michael Ruff, the Director of the ARS Office of Homeland Security, (202) 720-3973.

Exhibit C

Response to the Draft Report From the Animal and Plant Health Inspection Service

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MEMORANDUM FOR THE ACTING INSPECTOR GENERAL

THROUGH: Bill Hawks
Under Secretary Bill Hawks MAR 22 2002
Marketing and Regulatory Programs

FROM: Bobby R. Acord MAR 21 2002
Administrator

SUBJECT: Oversight and Security of Biological Agents at Laboratories Operated by the U.S. Department of Agriculture---Audit No. 50099-13-At

This correspondence is the Animal and Plant Health Inspection Service's (APHIS) reply to your draft audit report dated March 8, 2002. Each of the recommendations identified in OIG's report is addressed in the enclosed comments.

APHIS appreciates the opportunity to examine the contents of the document and submit our response prior to publication of the final version.

Enclosure

APHIS - Protecting American Agriculture

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Recommendation 1:

Hasten the implementation of the policies and procedures being prepared by the Department's biosecurity task force.

APHIS Response:

Our previous response indicated that policies would be implemented at all of our laboratories. Our safety officials and other personnel met with counterparts in ARS in December. A task force was formed to develop an implementation plan with completion dates for milestones.
The implementation plan for "USDA Security Policies and Procedures for Biosafety Level 3 Laboratories and Other Laboratories of Consequence" is still in development. APHIS has, however, initiated compliance with the recommendations and timelines of the draft document and will make necessary adjustments as the final version is completed.

Recommendation 2:

Direct all agencies to instruct all USDA laboratories to immediately compile a comprehensive listing of biological agents handled or stored at their respective facilities and to forward this listing to the agency's headquarters for consolidation at the Department level. This inventory record should include all laboratories by agency, showing the biosafety level for each facility and a current inventory, which easily identifies all biological agents. Ensure the inventory record is secure and can be readily accessed by managers at the headquarters level. Establish a date for accomplishing this task.

APHIS Response:

Our prior reply indicated that inventories would be transmitted to agency headquarters by January 31, 2002. We can now report that APHIS laboratories have completed an inventory of all stocks of pathogens of consequence and submitted this information to their respective program Deputy Administrators at headquarters. This was accomplished by target date, and the inventory lists are maintained in password-protected electronic format and/or in approved security safes. Access to information is restricted to authorized personnel only.

Recommendation 3:

Based on the inventory of biological agents for each facility, each agency should immediately assess the risk associated with such biological agents and determine commensurate biosafety and biosecurity level for such agents.

APHIS Response:

Our prior response stated that we would initiate risk assessment upon completion of the inventory process.

Recommendation 4:

Evaluate the results of security reviews conducted at two of the Department's BSL-3 laboratories (laboratories E and F) and begin implementing corrective actions related to security issues immediately. Arrange for security reviews of other USDA laboratories starting with level-3 facilities.

APHIS Response:

Our previous reply indicated that security guards and patrols were deployed at laboratory F. Physical security has been reviewed at APHIS laboratories, and corrective actions began shortly after September 11. Security advisories have been transmitted to all of our facilities by the Administrator and the MRP Business Services entity of the Agency.

Recommendation 5:

Immediately assess the feasibility of continuing current research and diagnostic activities at the facilities located in a strip mall.

APHIS Response:

Our earlier response said homeland security funding will enable the relocation of the strip mall facility to another location with a reduced risk to the public and where unauthorized entry can be more adequately assured. Since the audit, all pathogens of consequence have been removed from the strip mall facility to locked, controlled access freezers on the main laboratory campus. Funds have already been identified, and plans for relocating laboratories over to the main campus are being developed.

Recommendation 6: ARS is addressing this recommendation.

Recommendation 7:

Propose to the Secretary that one individual at the Department level be responsible for monitoring and reviewing the physical security at USDA laboratories to ensure security is adequate.

APHIS Response:

The draft audit report indicates this issue is pending with USDA agencies. We reiterate that pathogens of consequence at all APHIS laboratories are stored in locked freezers at secured facilities with access limited to authorized personnel. Security clearances will be obtained for those individuals.

Recommendation 8:

Immediately review security procedures to ensure access to high consequence biological agents is controlled and limited to authorized purposes. Institute management controls to ensure unauthorized removal does not occur by restricting access to facilities and laboratories handling or storing such high consequence biological agents only to personnel with authorized access and with appropriate identification and requiring specific tracking on inventory records any removal and return of samples of high level biological agents.

APHIS Response:

Our former reply provided timeframes to implement USDA policies and procedures which require restricting access to high consequence biological agents. APHIS laboratories have implemented procedures restricting access to pathogens of consequence to authorized personnel. Appropriate background checks and security clearances will be made for those individuals.

Recommendation 9:

Immediately determine the necessity for background checks and security clearances for those personnel having access to high level biological agents, particularly those with access to level-3 laboratories. Establish a protocol for approving authorized access to such materials. Also, work with the Department to reduce the backlog of security clearances.

APHIS Response:

The draft report states that the backlog of security clearances has been cleared at USDA, but OPM had not addressed about 400 of the clearances forwarded there for final approval. In collaboration with USDA's Office of Crisis Planning and Management, we determined that all positions at the laboratories referenced in the audit which have access to high level biological agents are designated, at a minimum, as "high risk public trust." This is the highest level of public trust position sensitivity. This designation connotes full-fledged background investigation. We have identified those individuals, and they are completing required paperwork. These documents will then be processed.

Recommendation 10:

Immediately issue a notice to all laboratory facilities with high level biological agents that they must report any improprieties or vandalism involving such materials to the agency's headquarters office which will in turn notify OIG and other relevant offices.

APHIS Response:

Our prior reply referenced departmental policies and procedures and the requirement to report intrusions at laboratories. APHIS laboratories have been provided written guidance on reporting incidents and suspicious activities. In addition, APHIS Biosafety Level 3 laboratories have developed a Biosecurity Incident Response Plan.

Exhibit D

Response to the Draft Report From the Food Safety and Inspection Service

DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

TO: Joyce N. Fleischman
Acting Inspector General

MAR 25 2002

FROM: Elsa A. Murano
Under Secretary
Food Safety

SUBJECT: Food Safety and Inspection Services (FSIS) Response to the March 2002, Office of Inspector General's (OIG) Draft Report – Oversight and Security of Biological Agents at Laboratories Operated by the U.S. Department of Agriculture, Audit Number 50099-13-At

Thank you for the opportunity to address the issues cited in the subject audit report. I understand that this audit report has been distributed to the Under Secretaries for Marketing and Regulatory Programs, Research, Education, and Economics, Natural Resources and Environment, the Department, and the Assistant Secretary for Administration for individual responses.

General Comments

In the Management Alert dated December 10, 2001, you noted our continued progress in maintaining security controls over our laboratories. You stated: "Only a few of the 88 sites we visited had materially increased security subsequent to September 11. An exception is FSIS, which has communicated information to its laboratories related to the concerns we raised in the September 24 management alert." This point should be reinstated in your draft report.

The report inaccurately concludes we have no plans to perform a risk assessment and have offered no timeframe for identifying the biosecurity measures needed at their respective laboratories. In fact, a risk assessment was performed by our laboratories. A team with representatives from the three Field Service Laboratories and the Microbial Outbreaks and Special Projects Laboratory was formed in September 2001. The team's assessment and critique of laboratory procedures and operations have enhanced the existing security plans and identified opportunities for us to institute additional controls. The resulting security plan addresses many of the key elements in the Department of Justice document, "Vulnerability Assessment of Federal Facilities," dated June 28, 1995. The laboratories generally comply with Level III.

FSIS has two laboratories in GSA facilities and one is in an USDA, ARS-owned facility. The three laboratories are rated at Biosafety Level Class II and follow the appropriate standards and guidelines. Upon receipt of biosecurity funding support and completion of plans, an additional laboratory is under consideration for facility enhancements to comply with Biosafety Level Class III.

In addition, we have reviewed this draft report and discussed it with our laboratory managers. FSIS will continue to communicate information to all of its laboratory personnel regarding OIG and other concerns to maintain a heightened security and safety awareness.

1. Recommendation No. 1:

Hasten the implementation of the policies and procedures being prepared by the Department's biosecurity task force.

Agency Response:

FSIS laboratories have recently obtained accreditation under the International Organization for Standardization (ISO), ISO/IEC 17025 (1999) General Requirements for the Competence of Testing and Calibration Laboratories. The FSIS laboratories have completed implementation of numerous policies, procedures, and safeguards that enhance security. These new requirements are for locks on all building and laboratory areas, freezers, and coolers to limit and control access to laboratories, samples, and pathogens. Additional measures included password protecting all essential laboratory computers to restrict unauthorized access.

The Assistant Deputy Administrator, Office of Public Health and Science has also established a laboratory security team consisting of representatives from all laboratories and it is chaired by the Scientific Advisor for the Laboratories. This group had numerous meetings to identify and evaluate security issues. Each of the four FSIS laboratories worked together and, as appropriate, separately, to develop extensive standard operating procedures that detail measures and controls needed to improve security for each laboratory. In addition, the laboratories will be required to regularly conduct internal audits to ensure that all security and control policies and procedures are being followed. The Assistant Deputy Administrator (ADA) has also mandated that the Quality Assurance Division audit the security plan of each laboratory during the annual QAD audit. As part of an effort to evaluate the current state of security of the system, in mid-October the ADA directed the QAD to conduct an unannounced audit at each of the FSIS laboratories. Several deficiencies were noted and promptly corrected.

This group has also drafted a Continuity of Operations Plan that details steps to be taken that will assist in carrying on the operations of the Laboratory System in the event of a local or national emergency. Included in this are plans to expand and enhance the capabilities of the FSIS laboratories for testing for selected biological and chemical agents in meat, poultry and egg products.

This will allow the FSIS laboratories to become a national resource that can be called upon during a bioterrorism incident. FSIS reaffirms its January 8, 2002, response to the Management Alert.

2. Recommendation No. 2:

   Direct all agencies to instruct all USDA laboratories to immediately compile a comprehensive listing of biological agents handled or stored at their respective facilities and to forward this listing to the agency's headquarters for consolidation at the Department level. This inventory record should include all laboratories, by agency, showing the biosafety level for each facility and a current inventory, which easily identifies all biological agents. Ensure that the inventory record is secure and can be readily accessed by managers at the headquarters level. Establish a date for accomplishing this task.

   Agency Response:

   All FSIS laboratories have maintained inventories of pathogens for several years. Two years ago FSIS expanded the inventory to include more information. After the September 11, 2001, tragedy, we asked the laboratories to check to ensure that the inventories were accurate and up-to-date. The inventories were forwarded to the Associate Deputy Administrator of the Office of Public Health and Science, FSIS. FSIS reaffirms its January 8, 2002, response to the Management Alert.

3. Recommendation No. 3:

   Based on the inventory of biological agents for each facility, each agency should immediately assess the risk associated with such biological agents and determine the commensurate biosafety and biosecurity level for such agents.

   Agency Response:

   The report inaccurately concludes we have no plans to perform a risk assessment and have offered no timeframe for identifying the biosecurity measures needed at their respective laboratories In fact a risk assessment was performed by our laboratories. A team with representatives from the laboratories was formed in September 2001.

   The team's assessment and critique of laboratory procedures and operations have enhanced the existing security plans and identified opportunities for us to institute additional controls. The resulting security plan addresses many of the key elements in the Department of Justice document, "Vulnerability Assessment of Federal Facilities," dated June 28, 1995. The laboratories generally comply with Level III.

   FSIS has laboratories in GSA facilities and one is in an USDA, ARS-owned facility. The three laboratories are rated at Biosafety Level Class II and follow the appropriate standards and guidelines. Upon receipt of biosecurity funding support and completion of plans, an additional laboratory is under consideration for facility enhancements to comply with Biosafety Level Class III.

4. Recommendation No. 4:

   Evaluate the results of security reviews conducted at two of the Department's BSL-3 laboratories (laboratories E and F) and begin implementing corrective actions related to security issues immediately. Arrange for security reviews of other USDA laboratories, starting with level-3 facilities.

   Agency Response:

   This recommendation is not applicable to FSIS.

5. Recommendation No. 5:

   Immediately assess the feasibility of continuing current research and diagnostic activities at the facilities located in a strip mall.

   Agency Response:

   This recommendation is not applicable to FSIS.

6. Recommendation No. 6:

   Take immediate action to correct the deficiencies at laboratory B, including the problems in inventory of biological agents, containment procedures, and physical security.

   Agency Response:

   This recommendation is not applicable to FSIS.

7. Recommendation No. 7:

   Propose to the Secretary that one individual at the Department level be responsible for monitoring and reviewing the physical security at USDA laboratories to ensure the security is adequate.

   Agency Response:

   FSIS agrees to consider the merits of an individual at the Departmental level being responsible for monitoring and reviewing the physical security at the USDA laboratories to ensure the security is adequate. Such an individual could serve as a liaison between each USDA agency and share "lessons learned."

8. Recommendation No. 8:

Immediately review security procedures to ensure access to high consequence biological agents is controlled and limited to authorized purposes.

Institute management controls to ensure unauthorized removal does not occur by restricting access to facilities and laboratories handling or storing such high consequence biological agents only to personnel with authorized access and with the appropriate identification and requiring specific tracking on inventory records any removal and return of samples of high-level biological agents.

Agency Response:

See the FSIS response to recommendation No. 3.

9. Recommendation No. 9:

Immediately determine the necessity for background checks and security clearances for those personnel having access to high-level biological agents, particularly those with access to level-3 laboratories. Establish a protocol for approving authorized access to such materials. Also, work with the Department to reduce the backlog of security clearances.

Agency Response:

This recommendation is not applicable to FSIS.

10. Recommendation No. 10:

Immediately issue a notice to all laboratory facilities with high-level biological agents that they are to report any improprieties or vandalism involving such materials to the agency's Headquarters office, which will in turn notify the Office of Inspector General and the other relevant offices.

Agency Response:

This recommendation is not applicable to FSIS.

If you have any questions, please have your staff contact Vincent Fayne, Internal Control Staff at (202) 720-5959.

cc:
M. Glavin, OA
L. Swacina, OA
J. Axtell, OM
E. Walker, OPHS
P. McCaskey, OPHS
J. Riggins, OPPDE
W. Smith, OFO
C. Seymour, OFO
P. Thompson, TSC
K. Elane, PS
V. Randecker, ASD
T. Wright, ASD
B. Quick, CPA
H. Reuben, OGC

Exhibit E

Response to the Draft Report From the Forest Service

United States Department of Agriculture
Forest Service
Washington Office
14th & Independence SW
P.O. Box 96090
Washington, DC 20090-6090

INFORMATION MEMORANDUM FOR JOYCE N. FLEISCHMAN, ACTING INSPECTOR GENERAL

THROUGH: For Mark Rey
Under Secretary, NRE

FROM: pa Dale N. Bosworth
Chief

Sally Collins 3/19/02

SUBJECT: Oversight and Security of Biological Agents at Laboratories Operated by the U.S. Department of Agriculture, OIG Audit Report No. 50099-13-At

We have reviewed the draft report for the subject audit. As indicated in the Executive Summary, page i of the report, the objective of the audit was to determine the extent and location of agents that are pathogenic to humans or injurious to agriculture and the adequacy of safeguards to ensure the security of these agents. As we indicated in our response to the earlier Management Alert on the subject, the Forest Service laboratories do not house these types of agents. We have a single laboratory that contains small quantities of an agent that is injurious to insects.

Nonetheless, we do have the following comments concerning the content of the draft report:

1- Recommendation No. 1: The Forest Service will, immediately upon issuance of the USDA policy and procedures concerning laboratory security, implement the requirements of those policies and procedures. We do not have laboratories that are classified BSL1, BSL2 or BSL3. We previously reported organisms at BSL1, but upon review by the USDA Facilities and Other Infrastructure Work Group it was determined these were not of a BSL character.

2- Recommendation No. 2: The Forest Service has no BSL biological agents. Therefore no inventory is appropriate. Forest Service laboratories do work with plant and insect disease organisms. These agents are not dangerous to humans. An inventory of kind and location is being requested and will be consolidated at Forest Service headquarters. This inventory will be forwarded to USDA by June 1, 2002. An inventory of amount of each organism is inappropriate because this can change on a daily basis as organisms are cultured for research studies or cultures are destroyed when studies are completed.

3- Recommendation No. 3: Physical security risk assessments are being conducted or have been completed at most facilities. Corrective measures will be implemented in response to assessment findings. Since no BSL agents are present, there is no need to determine biosafety or biosecurity levels.

4- Recommendation No. 4: Not applicable to the Forest Service.

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5- Recommendation No. 5: Not applicable to the Forest Service.

6- Recommendation No. 6: Not applicable to the Forest Service.

7- Recommendation No. 7: Not applicable to the Forest Service.

8- Recommendation No. 8: High consequence biological agents are not present in Forest Service laboratories therefore this recommendation is not applicable.

9- Recommendation No. 9: The Forest Service does not utilize high-level biological agents in its laboratories therefore this recommendation is not applicable.

10- Recommendation No. 10: Forest Service laboratories do not contain high-level biological agents therefore this recommendation is not applicable.

Any questions concerning this information may be directed to Dr. Bov Eav, Associate Deputy Chief, Research and Development. Dr. Eav's telephone number is (202) 205-1702.

Exhibit F

Response to the Draft Report From the Agricultural Marketing Service

USDA

United States
Department of
Agriculture

Marketing and
Regulatory
Programs

Agricultural
Marketing
Service

P.O.Box 96456
Washington, DC
20090-6456

MAR 18 2002

TO: Joyce Fleischman
Acting Inspector General
Office of Inspector General

THROUGH: Bill Hawks James Butler
for Under Secretary
Marketing and Regulatory Programs

FROM: A.J. Yates
Administrator
Agricultural Marketing Service

March 15, 2002

SUBJECT: Oversight and Security of Biological Agents at Laboratories Operated by the U.S. Department of Agriculture

Background

This memorandum responds to your request dated March 8, 2002, requesting written comments on the draft of the subject audit report. We have listed each of the recommendations below along with our response. Additionally, we have provided a general comment concerning the correct biosafety classification at one of AMS' laboratories.

Recommendation No. 1:

Hasten the implementation of the policies and procedures being prepared by the Department's biosecurity task force.

AMS Response:

AMS currently has in place an SOP for the handling and storage of biological materials. We feel based on the level (BSL-2) of the materials within AMS, this SOP is sufficient. However, AMS is currently developing a new chapter to be included in our *AMS Safety and Occupational Health Handbook* addressing biosafety/security. The *USDA Biosecurity Requirements for Biosafety Level 3 Pathogens and Facilities* policies and procedures document is being used as general guidance.

Recommendation No. 2:

Direct all agencies to instruct all USDA laboratories to immediately compile a comprehensive listing of biological agents handled or stored at their respective facilities and to forward this listing to the agency's headquarters for consolidation at the Department level. This inventory record should include all laboratories, by agency, showing the biosafety level for each facility and a current inventory, which easily identifies all biological agents. Ensure that the inventory record is secure and can be readily accessed by managers at the headquarters level. Establish a date for accomplishing this task.

AMS Response:

AMS has an updated inventory of biological agents handled and stored at our facilities. This list is maintained at each facility with copies forwarded to AMS headquarters.

Recommendation No. 3:

Based on the inventory of biological agents for each facility, each agency should immediately assess the risk associated with such biological agents and determine the commensurate biosafety and biosecurity level for such agents.

AMS Response:

AMS does not handle or store BSL-3 or high consequence materials. AMS feels current security and safety measures in place are sufficient for materials handled and stored (BSL-2).

Recommendation No. 4

Evaluate the results of security reviews conducted at two of the Department's BSL-3 laboratories (laboratories E and F) and begin implementing corrective actions related to security issues immediately. Arrange for security reviews of other USDA laboratories, starting with level-3 facilities.

AMS Response:

Not applicable to AMS as no BSL-3 materials stored or handled.

Recommendation No. 5:

Immediately assess the feasibility of continuing current research and diagnostic activities at the facilities located in a strip mall.

AMS Response:

Not applicable to AMS.

Recommendation No. 6:

Take immediate action to correct the deficiencies at laboratory B, including the problems in inventory of biological agents, containment procedures, and physical security.

AMS Response:

Not applicable to AMS.

Recommendation No. 7:

Propose to the Secretary that one individual at the Department level be responsible for monitoring and reviewing the physical security at USDA laboratories to ensure the security is adequate.

AMS Response:

AMS concurs with this recommendation.

Recommendation No. 8:

Immediately review security procedures to ensure access to high consequence biological agents is controlled and limited to authorized purposes. Institute management controls to ensure that unauthorized removal does not occur by restricting access to facilities and laboratories handling or storing such high consequence biological agents only to personnel with authorized access and with the appropriate identification and requiring specific tracking on inventory records any removal and return of samples of high-level biological agents.

AMS Response:

AMS does not handle or store materials considered to be high consequence biological agents.

Recommendation No. 9:

Immediately determine the necessity for background checks and security clearances for those personnel having access to high-level biological agents, particularly those with access to level-3 laboratories. Establish a protocol for approving authorized access to such materials. Also, work with the Department to reduce the backlog of security clearances.

AMS Response:

Not applicable as AMS has no level-3 biological agents.

Recommendation No. 10:

Immediately issue a notice to all laboratory facilities with high-level biological agents that they are to report any improprieties or vandalism involving such materials to the agency's Headquarters office, which will in turn notify the Office of the Inspector General and other relevant offices.

AMS Response:

Not applicable as AMS does not have materials considered to be high-level biological agents.

General Comment(s):

AMS would like to take this opportunity to clarify what we believe was a miscommunication between AMS headquarters staff and your auditor, (page 9 last paragraph). The information provided to your auditor was based on the definition given to our staff by your auditor. The auditor asked about high level biological materials. The AMS response was that our laboratory does not handle or store such biological materials. The response was in no way intended to mean we have no biological material. The response merely addressed the question asked. We believe the mischaracterization resulted from poor communication between OIG and AMS staff, and incorrectly suggests that there was confusion with AMS concerning the presence of biological materials in one of our laboratories.

cc: Richard D. Long
Assistant Inspector General
for Audit

Copies of this report have been distributed to:

Under Secretary, Marketing and Regulatory Programs	(2)
Under Secretary, Research, Education, and Economics	(2)
Under Secretary, Food Safety	(2)
Under Secretary, Natural Resources and Environment	(2)
Assistant Secretary, Administration	(1)
Attn: Agency Liaison Officer	(3)
Administrator, AMS	(1)
Attn: Agency Liaison Officer	(6)
Administrator, APHIS	(1)
Attn: Agency Liaison Officer	(9)
Acting Administrator, ARS	(1)
Attn: Agency Liaison Officer	(6)
Acting Administrator, FSIS	(1)
Attn: Agency Liaison Officer	(10)
Chief, FS	(1)
Attn: Agency Liaison Officer	(10)
General Accounting Office	(1)
Office of the Chief Financial Officer	
Director, Planning and Accountability Division	(1)
Director, Office of Crisis Planning and Management	(1)
Director, Office of Procurement and Property Management	(1)